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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/630,884	07/30/2003	Kazunori Taniguchi	P/3541-39	7938

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EXAMINER	
BACHMAN, LINDSEY MICHELE	
ART UNIT	PAPER NUMBER
3734	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	02/05/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/630,884	TANIGUCHI ET AL.	
	Examiner	Art Unit	
	Lindsey Bachman	3734	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 September 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-5,7-17 and 19-32* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5,7-17 and 19-32* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *26 September 2006* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

This action is in response to Applicant's amendment filed on 26 September 2006.

Drawings

1. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the support, the base member, the elongate member and the extended portion in Claim 1 must be shown or the feature(s) canceled from the claim(s). It is not clear to the Examiner in light of the specification what each part in the claims corresponds to in the drawings. No new matter should be entered.

2. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner,

the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Specification

3. The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: Claim 30 refers to a "rotation mechanism". This term is not used in the specification.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claim 1, 4, and 5 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

6. Claim 4 states that the elongate member is sheath. Claim 1 states that the elongate member has a base member on the distal end. It is not clear from the drawings and specification how the base member is located on the distal end of the elongate member. The drawings indicate that the base member is located near the distal end of

the sheath/elongate member when the device is assembled; however the base member is located (and attached) on the distal end of the extended portion.

7. Claim 5 states that the extended portion has a slope inclined an axis of the sheath. This slope is not apparent from the drawings, nor is it described in the specification. Applicant states that the extended portion 115a is sloped with respect to the axis of the sheath 5, as in Figure 12. In Figure 12, the longitudinal axis of element 115a is parallel with the longitudinal axis of the sheath.

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. Claim 9 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

10. Claim 9 is not clear because Examiner does not understand what Applicant intends to claim in lines 3-4. Specifically, it is not clear how the extended portion has a tube that is cut from the sheath. Further clarification is needed.

Claim Rejections - 35 USC § 102

11. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

12. Claims 29-32 are rejected under 35 U.S.C. 102(b) as being anticipated by Wallace, et al. (US Patent 6,394,998).

13. Claims 29 and 32: Wallace'998 teaches a surgical instrument that contains an insertion section (see Figure 3a) that is covered with a sheath (14.3) that includes a notch (17 in Figure 7) on the distal end. The device also contains a treatment section (50) connected to the distal end of the insertion section (see Figures 5-7) and an operation section (53) that is located at the proximal end of the insertion section and operated by an operator (column 7, lines 1-37).

14. Claim 30: The treatment section has a rotation mechanism (68, 70) to rotate the treatment section with respect to the insertion section (column 7, line 66 to column 8, line 39 and column 9, lines 6-19). The notch is disposed within the rotational range of the treatment section (see Figure 7).

15. Claim 31: The insertion section and the treatment section have conductive areas to supply high-frequency power to the treatment section (column 16, line 29 to column 17, line 33). Further, the sheath (referred to in the text now as 114.1) is insulating (column 17, line 33-53).

Claim Rejections - 35 USC § 103

16. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

17. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

18. Claims 1-5, 7-17, 19-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lee, et al. (US Patent 6,554,844), in further view of Miyawaki, et al. (US Patent 6,066,151).

19. Claims 1, 2, 3, 4 and 5: Lee'844 discloses a device that contains an end effecter (602, 603); a support (601) in which the proximal end (towards 626) supports the end effecter; a base member (600) which pivotally supports (around axis 604/pin 620) the proximal end of the support on its distal end (towards 620) so that the support can rotate along with the end effecter (see Figure 3a). The device also contains an extended portion (300, 302, 303) that has a proximal end and a distal end; the base member is attached to the distal end of the extended portion.

20. Lee'844 does not disclose an elongate member/sheath.

21. Miyawaki'151 teaches a similar device that contains a base member (100) that supports the support (103) and end effecters (105, 113). Miyawaki also teaches an elongate member (31). Assembled, the base member (100) is located at the distal end of the elongate member (see Figure 1). Further, Miyawaki'151 teaches an extended

portion (71) that is disposed in/integral with the distal end of the elongate member (Figure 1 and 2) and is extendable with respect to a base member. Also, the elongate member is a sheath that is integral with the extended portion (see Figure 1). The extended portion (71) has a slope relative to the longitudinal axis of the sheath. It would have been obvious to one skilled in the art at the time the invention was made to modify extended portion taught by Lee'844 by covering it with a sheath as taught by Miyawaki'151 in order to aid in inserting the endoscopic portion of the device into the body, as is well known in the art.

22. Claim 7: Miyawaki'151 teaches that the sheath is rigid (column 5, lines 16-19) and the extended portion is rigid (column 6, lines 33-40). The sheath is rigid because it protects the extended portion (column 5, lines 16-39). The extended portion is rigid because it is needed to transfer energy to the distal end and a flexible device would absorb all the energy. It would have been obvious to one skilled in the art at the time the invention was made to modify the device taught by Lee'844 with the rigid members taught by Miyawaki'151 in order to apply adequate force/pressure on the tissue being treated.

23. Claims 8 and 11: Miyawaki'151 teaches that the elongate member and the end effecter have conductive areas to apply high frequency power to the end effecter (column 5, lines 16-19, column 6, lines 33-56, and column 8, lines 45-51). Further, the sheath has an inner tube and an insulating outer tube (column 5, lines 16-19). It would have been obvious to one skilled in the art to modify the device taught by Lee'844 by applying high frequency power as taught by Miyawaki'151 in order to aid in cutting body

tissue. Further, it would be obvious to use an insulated sheath to protect the body areas not being treated from the power.

24. Claim 9: Miyawaki'151 teaches a circular shaped sheath because it is well known in the art that circular shapes are easier to insert in the body than other shapes. Miyawaki'151 teaches that the extended portion inherently has a slope (any tangent line around the tube) relative to the sheath. It would have been obvious to one skilled in the art at the time the invention was made to modify the device taught by Lee'844 with a circular sheath because it is well known that circular shapes are easier to insert into the body than other shapes because they do not have corners that concentrate stresses in the tissue.

25. Claim 10: Miyawaki'151 teaches a circular shaped sheath and that the extended portion (71) has a circular arc shape (portion of circular cross section). It is well known in the art that circular shapes are easier to insert in the body than other shapes because circles to not have corners which would be areas that concentrate stresses with placed in the body. It would have been obvious to one skilled in the art at the time the invention was made to use an insertion portion with a circular cross section because it is easier to insert into the body than a device with a different shaped cross section.

26. Claim 12: Lee'844 teaches an operation section (300, 302, 303) that rotates the end effecter and the support (column 8, lines 32-42) (The operation section contains wheels 330, 332, 334 that are connected to cables 606-609. The cables rotated the end effecter and the support.). The insertion section has first (608, 609) and second (606, 607) driving members that are arranged side by side (in portion 302, 303). The first

driving members operate the end effector (column 6, lines 33-53) and the second driving members operate the support (column 6, lines 22-33).

27. Claim 13: The end effectors taught by Lee'844 are a pair of jaws that can be opened and closed (Figure 3a). The jaws are supported by the support (at 624) (Figure 3b). The support is connected to the distal end of the second driving member to rotate the support in one plane (see Figure 3a, 3b, and arrow J5).

28. Claim 14: Lee'844 teaches a sliding member (610, 611) that is supported by one jaw (Figure 3b) and slid to open/close the jaws (column 6, lines 33-54). There is connection member (round base, as shown in Figure 3b that supports the cables 610, 611. Round base cannot be seen in Figure 3b for cables 610, 611, see equivalent around 608, 609.). The connection member is connected to the sliding member (see Figure 3b) and the distal end of the first driving member (608, 609) (when the device is assembled (see Figure 3a).

29. Claims 15 and 16: Lee'844 does not teach a conductive first driving member (608, 609) or an insulating sheath.

30. Miyawaki'151 teaches that the elongate member and the end effecter have conductive areas to apply high frequency power to the end effecter (column 5, lines 16-19, column 6, lines 33-56, and column 8, lines 45-51). It would be obvious to make the member that moves the end effecter (first driving member) conductive as well because the power needs to be transmitted from the proximal end of the device to the distal treating end of the device. Further, the sheath an insulating outer tube (column 5, lines 16-19). It would have been obvious to one skilled in the art to modify the device taught

by Lee'844 by applying high frequency power as taught by Miyawaki'151 in order to aid in cutting body tissue. Further, it would be obvious to use an insulated sheath to protect the body areas not being treated from the power.

31. Claim 17: Miyawaki'151 teaches an attaching/detaching mechanism (32, 33) in order to remove the sheath (column 4, line 62 to column 5, line 6). It would have been obvious to one skilled in the art at the time the invention was made to add a attaching/detaching mechanism to the sheath in order to remove it after use for cleaning/replacement.

32. Claim 19: Lee'844 teaches an end effecter operation section (332, 334) that is disposed within the elongate member (column 8, lines 5-42) to operate the end effecter (332 and 334 are connected to 608, 609 and 610, 611) and a rotation operation section (330) that is disposed within the proximal end of the elongate member to rotate the support (601) via cables 606, 607 (column 8, lines 27-33).

33. Claim 20: Lee'844 discloses a first transmitting member (608-611) that has distal and proximal ends. The proximal end is dynamically connected to the end effecter operation section (332, 334) (column 8, lines 32-42 and Figure 4) and the distal end is dynamically connected to the end effecter (see Figure 3b). There is also a second transmitting member (606, 607) in which the proximal end is connected to the rotation operation section (330) (column 8, lines 32-42 and Figure 4) and the distal end is connected to the support (601) (column 8, lines 27-33).

34. Claim 21: Lee'844 teaches the first transmitting member has a first part (proximal end) disposed in the elongate member (column 8, lines 32-43) and a second part (distal end) disposed in the support (601) (near element 630 in Figure 3b).

35. Claim 22: Lee'844 does not teach an elongate member sheath. Miyawaki'151 teaches that the elongate member is a sheath. Further, it is inherent that if the device taught by Lee'844 were modified with a sheath over sections 302, 303, the first and second transmitting members would pass though it. It would have been obvious to one skilled in the art at the time the invention was made to modify extended portion taught by Lee'844 by covering it with a sheath as taught by Miyawaki'151 in order to aid in inserting the endoscopic portion of the device into the body, as is well known in the art.

36. Claims 23 and 24: Lee'844 discloses that the support (601) contains a pivot (around axis 605) and the end effecter is supported by and rotated around the pivot (axis 605, pin 624; see column 6, lines 16-22).

37. Claim 25: Lee'844 discloses an opening/closing section (332, 334) that is disposed within the elongate member (column 8, lines 5-42) to operate the jaws (332 and 334 are connected to 608, 609 and 610, 611) and a rotation operation section (330) that is disposed within the proximal end of the elongate member to rotate the support (601) via cables 606, 607 (column 8, lines 27-33).

38. Claim 26: Lee'844 discloses a first transmitting member (608-611) that has distal and proximal ends. The proximal end is dynamically connected to the end effecter operation section (332, 334) (column 8, lines 32-42 and Figure 4) and the distal end is dynamically connected to the end effecter (see Figure 3b). There is also a second

transmitting member (606, 607) in which the proximal end is connected to the rotation operation section (330) (column 8, lines 32-42 and Figure 4) and the distal end is connected to the support (601) (column 8, lines 27-33).

39. Claim 27: Lee'844 teaches the first transmitting member has a first part (proximal end) disposed in the elongate member (column 8, lines 32-43) and a second part (distal end) disposed in the support (601) (near element 630 in Figure 3b).

40. Claim 28: Lee'844 does not teach an elongate member sheath. Miyawaki'151 teaches that the elongate member is a sheath. Further, it is inherent that if the device taught by Lee'844 were modified with a sheath over sections 302, 303, the first and second transmitting members would pass though it. It would have been obvious to one skilled in the art at the time the invention was made to modify extended portion taught by Lee'844 by covering it with a sheath as taught by Miyawaki'151 in order to aid in inserting the endoscopic portion of the device into the body, as is well known in the art.

Response to Arguments

Applicant's arguments with respect to Claims 1-32 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lindsey Bachman whose telephone number is 571-272-

6208. The examiner can normally be reached on Monday to Thursday 7:30 am to 5 pm, and alternating Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hayes can be reached on 571-272-4959. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

lb

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